



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0626. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE-14526, Silver Spring, MD 20993-0002 PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act--21 U.S.C. 343(r)(6) (OMB Control Number 0910-0626)--Extension

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. Under section 403(r)(6)(A) of the FD&C Act, such a statement is one that “claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption for a nutrient or dietary ingredient.”

The guidance document, entitled “Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act,” provides our recommendations to manufacturers about the amount, type, and quality of evidence they should have to substantiate a claim under section 403(r)(6) of the FD&C Act. The guidance does not discuss the types of claims that can be made concerning the effect of a dietary supplement on the structure or function of the body, nor does it discuss criteria to determine when a statement about a dietary supplement is a disease claim. The guidance document is intended to assist manufacturers in their efforts to comply with section 403(r)(6) of the FD&C Act. Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/FoodGuidances>.

Dietary supplement manufacturers collect the necessary substantiating information for their product as required by section 403(r)(6) of the FD&C Act. The guidance provides information to manufacturers to assist them in doing so. The recommendations contained in the guidance are voluntary. Dietary supplement manufacturers will only need to collect information to substantiate their product's nutritional deficiency, structure/function, or general well-being claim if they choose to place a claim on their product's label.

The standard discussed in the guidance for substantiation of a claim on the labeling of a dietary supplement is consistent with standards set by the Federal Trade Commission for dietary supplements and other health-related products that the claim be based on competent and reliable scientific evidence. This evidence standard is broad enough that some dietary supplement manufacturers may only need to collect peer-reviewed scientific journal articles to substantiate their claims; other dietary supplement manufacturers whose products have properties that are less well documented may have to conduct studies to build a body of evidence to support their claims. It is unlikely that a dietary supplement manufacturer will attempt to make a claim when the cost of obtaining the evidence to support the claim outweighs the benefits of having the claim on the product's label. It is likely that manufacturers will seek substantiation for their claims in the scientific literature.

The time it takes to assemble the necessary scientific information to support their claims depends on the product and the claimed benefits. If the product is one of several on the market making a particular claim for which there is adequate publicly available and widely established evidence supporting the claim, then the time to gather supporting data will be minimal; if the product is the first of its kind to make a particular claim or the evidence supporting the claim is

less publicly available or not widely established, then gathering the appropriate scientific evidence to substantiate the claim will be more time consuming.

In the Federal Register of November 4, 2014 (79 FR 65409), FDA published a 60-day notice requesting public comment on the proposed collection of information. Five comments were received. One comment agreed with the Agency's burden estimate while the remaining comments were not responsive to four information collection topics solicited in the notice and are therefore not discussed in this document.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden¹

Claim Type	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Widely known, established	667	1	667	44	29,348
Pre-existing, not widely established	667	1	667	120	80,040
Novel	667	1	667	120	80,040
Total					189,428

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We assume that it will take 44 hours to assemble information needed to substantiate a claim on a particular dietary supplement when the claim is widely known and established. We believe it will take closer to 120 hours to assemble supporting scientific information when the claim is novel or when the claim is pre-existing but the scientific underpinnings of the claim are not widely established. These are claims that may be based on emerging science, where conducting literature searches and understanding the literature takes time. It is also possible that references for claims made for some dietary ingredients or dietary supplements may primarily be found in foreign journals and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases,

such as the National Library of Medicine's literature database, all of which increases the time of obtaining substantiation.

In the Federal Register of January 6, 2000 (65 FR 1000), we published a final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. In that final rule, we estimated that there were 29,000 dietary supplement products marketed in the United States (65 FR 1000 at 1045). Assuming that the flow of new products is 10 percent per year, then 2,900 new dietary supplement products will come on the market each year. The structure/function final rule estimated that about 69 percent of dietary supplements have a claim on their labels, most probably a structure/function claim (65 FR 1000 at 1046). Therefore, we assume that supplement manufacturers will need time to assemble the evidence to substantiate each of the 2,001 claims ($2,900 \times 69$ percent) made each year. If we assume that the 2,001 claims are equally likely to be pre-existing widely established claims, novel claims, or pre-existing claims that are not widely established, then we can expect 667 of each of these types of claims to be substantiated per year. Table 1 of this document shows that the annual burden hours associated with assembling evidence for claims is 189,428 (the sum of 667×44 hours, 667×120 hours, and 667×120 hours).

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.